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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,924	11/28/2005	David Wohlrab	234988	5291

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EXAMINER	
HENRY, MICHAEL C	
ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,924	WOHLRAB, DAVID	
	Examiner	Art Unit	
	Michael C. Henry	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-22 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 04/01/05, 05/31/05 & 03/01/06.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-22 are pending in application

Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 provides for "the use of hyaluronic acid, ..." but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Dependent claims 16-22 which also recite the use of, are also encompassed by this rejection.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 15 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F.

Supp. 131, 149 USPQ 475 (D.D.C. 1966). Dependent claims 16-22 which also recite the use of, are also encompassed by this rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

A written description analysis involves three principle factors:

(1) field of the invention

(2) breath of the claims, and

(3) possession of the claimed invention at the time of filing for each claimed species/genus based upon the teachings of the specificaiton and the field of the invention.

The Federal Circuit court stated that written description of an invention "requires a precise definition, such as by structure, formula, or chemical name, of the claimed subject matter sufficient to distinguish it from other material". University of California v. Eli Lilly and Co., 43 USPQ2d 1398 (Fed Cir. 1997). The court also stated "Naming a type of material generally known to exist, in the absence as to what the material consists of is not a definition of that material". Id. Further, the court stated that to adequately describe a claimed genus, adequate

must describe a representative number of species of the claimed genus, and that one skilled in the art should be able to "visualize or recognize the identity of the members of the genus". Id .

(A) Provide a brief backdrop of the field of the invention. A reference from the BACKGROUND might very well be sufficient.

(B) Outline the scope and content of the claims briefly

(C) At the time of filing, from the disclosure, does it appear applicants were indeed in possession of the claimed invention?

The claims are drawn to a composition consisting of at least one active agent from the group hyaluronic acid, the salts and fragments thereof, an active agent B from the group of local anaesthetics and derivatives thereof and if necessary further additives for human and veterinary medical therapy, prophylaxis and/or metaphylaxis of degenerative or traumatic articular diseases and articular function disorders and also articular cartilage and cartilage bone defects. The examiner notes that the knowledge and level of skill in this art would not permit one skilled in this art to prepare applicants composition (as claimed) which has the effect of preventing (prophylaxis and/or metaphylaxis) degenerative or traumatic articular diseases and articular function disorders and also articular cartilage and cartilage bone defects, since prevention said diseases or conditions is not generally known in the art, and consequently, the skilled artisan could not immediately envisage the invention claimed. Applicants claims are drawn to the said composition for preventing (prophylaxis and/or metaphylaxis) degenerative or traumatic articular diseases and articular function disorders and also articular cartilage and cartilage bone defects, which is not generally known to exist in this art; additionally, the disclosure is silent with regard to that which makes up and identifies how the said composition can prevent the said diseases, which is seen to be lacking a clear description via art recognized

procedural and methodological steps. In addition, the prevention of such diseases does not have a single recognized cause. In fact, the aforementioned conditions or diseases, are recognized as having many contributing factors, ranging from hereditary considerations, to lifestyle choices such as the diet and maintenance of bodily healthiness which includes (1) injury (2) metabolic disorders (e.g., hyperparathyroidism) (3) obesity or being overweight is a risk factor for knee osteoarthritis (4) Bony growths (osteophytes) on the spine in the neck region or in the lower back and (5) family history of the disease. These are only a few of the factors that promote these diseases or conditions in people. For example, osteoarthritis (degenerative articular disease) which is also known as degenerative arthritis has several contributing factors or causes which includes aging, hereditary factors, obesity, repeated trauma or surgery to the joint structures, abnormal joints at birth (congenital abnormalities), gout, diabetes and other hormone disorders. Applicant has not provided a description as how any cause (like the aforementioned) can be prevented, much less a description of how the said disease, condition or defect can be prevented. Furthermore, Applicant has not provided any clear description via art recognized procedural and methodological steps. Moreover, Applicant has not provided an adequate representation of the mode of treatment of said diseases to provide a full, clear and precise indication that applicant is in possession of the members of the methodological and procedural steps which would enable the skilled artisan to practice this invention by preparing the said composition which can prevent said diseases or conditions. It should be noted that claims 2-14 which are drawn to said composition for preventing the said diseases or conditions are also encompassed by the aforementioned rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Romeo et al. (US 6,224,857 B1).

In claim 1, applicant claims a combination preparation consisting of at least one active agent from the group hyaluronic acid, the salts and fragments thereof, an active agent B from the group of local anaesthetics and derivatives thereof and if necessary further additives for human and veterinary medical therapy, prophylaxis and/or metaphylaxis of degenerative or traumatic articular diseases and articular function disorders and also articular cartilage and cartilage bone defects. Romeo et al. disclose applicant's composition consisting of the active agent, hyaluronic acid, and an active agent benzydamine or bupivacaine that is a local anaesthetic (see abstract, col. 2, lines 15-38 and Claims 1-9). Claim 2 is drawn to the composition of Claim 1 wherein the active agents A and B are bonded to each other chemically or physically, and in that the active agent B can be released in a delayed manner. Romeo et al. disclose applicant's composition wherein the active agents are bonded to each other chemically (ionically) (see abstract, col. 2, lines 15-38 and Claims 1-9). It should be noted that Romeo et al.'s composition is the same as applicant's composition with the same active agents and with the same type of bonding and therefore it should inherently possess property or effect of been able to release the active agent (local anaesthetic) in a delayed manner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Romeo et al. (US 6,224,857 B1).

In claim 1, applicant claims a combination preparation consisting of at least one active agent from the group hyaluronic acid, the salts and fragments thereof, an active agent B from the group of local anaesthetics and derivatives thereof and if necessary further additives for human and veterinary medical therapy, prophylaxis and/or metaphylaxis of degenerative or traumatic articular diseases and articular function disorders and also articular cartilage and cartilage bone defects. Claims 3-4 are drawn to a composition according to claim 1, wherein the active agents are present in specific concentration ranges.

Romeo et al. disclose applicant's composition consisting of the active agent, hyaluronic acid, and an active agent benzydamine or bupivacaine that is a local anaesthetic (see abstract, col. 2, lines 15-38 and Claims 1-9). Furthermore, Romeo et al. disclose that their composition or salts which includes benzydamine salts of hyaluronic acid are advantageous for application in ophthalmology. In addition, Romeo et al. disclose that their composition can be applied in the field or treatment of traumatic and degenerative-inflammatory processes in the joints (i.e., traumatic and degenerative articular diseases) (see col. 3, lines 10-27).

The difference between applicant's claimed composition and the composition of Romeo et al. is the amounts or quantities of the active agents in the composition. However, the preparation of different amounts, quantities or concentration of the active agents in the composition depends on factors like the severity of condition or diseases (e.g., the traumatic and degenerative-inflammatory processes in the joints or traumatic and degenerative articular disease) treated and the type, age and weight of the subject treated.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared a composition of Romeo et al. of different amounts, quantities or concentration of the active agents to treat conditions or diseases such as the degenerative-inflammatory processes in the joints or traumatic and degenerative articular disease, based on need, like the severity of said condition or disease treated and the type, age and weight of the is subject treated.

One having ordinary skill in the art would have been motivated to prepare a composition of Romeo et al. of different amounts, quantities or concentration of the active agents to treat conditions or diseases such as the degenerative-inflammatory processes in the joints or traumatic and degenerative articular disease, based on need, like the severity of said condition or disease treated and the type, age and weight of the is subject treated.

Claims 5-14 are drawn to a composition according to claim 1, wherein specific agents are contained as additives.

Romeo et al. disclose applicant's composition consisting of the active agent, hyaluronic acid, and an active agent benzydamine or bupivacaine that is a local anaesthetic (see abstract, col. 2, lines 15-38 and Claims 1-9). Furthermore, Romeo et al. disclose that their salts

hyaluronic acid which includes benzydamine salts of the present invention, besides their advantageous application in ophthalmology, like the other anaesthetic bases, have proved to be new drugs with a very wide field of application, for example in inflammatory processes in the mouth or airways such as stomatitis of various origin, tonsillitis or tracheitis, in mucositis caused by radio- or chemotherapy, by sub or diagnostic intubation, such as bronchoscopy, in dental and gingival disorders in general, including teething trouble in babies, in rhinitis, in inflammatory processes affecting the auditory canal, in conjunctivitis of various origin, in proctological conditions, in traumatic and degenerative-inflammatory processes in the joints, in vulvovaginitis and urethritis of various kinds, including those caused by radio- and chemotherapy, surgical operations, diagnostic manoeuvres, childbirth and, in general, any inflammatory disorder of any kind (see col. 3, lines 10-27).

The difference between applicant's claimed composition and the composition of Romeo et al. are the additives in the composition. However, Romeo et al.'s disclose that their composition has a very wide field of application and therefore the addition of specific type additives depends on factors like the type and severity of condition or diseases treated.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared a composition of Romeo et al. containing different additives, to treat the different conditions or diseases disclosed by Romeo et al. such as the traumatic and degenerative-inflammatory processes in the joints or traumatic and degenerative articular disease, depending on factors, like the type and severity of condition or disease treated.

One having ordinary skill in the art would have been motivated to prepare a composition of Romeo et al. containing different additives, to treat the different conditions or diseases

disclosed by Romeo et al. such as the traumatic and degenerative-inflammatory processes in the joints or traumatic and degenerative articular disease, depending on factors, like the type and severity of condition or disease treated. It should be noted that the different physical formulations of active ingredients like hyaluronic acid and benzydamine or bupivacaine that are prepared by the use of other art recognized additive or excipents such as preservatives, antioxidants, inhibitors, anti-infective agents and vehicles is well within the purview of an ordinary artisan.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

9/12/07

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Art Unit 1623

September 7, 2007.